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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,869	11/28/2000	Juha Punnonen	18097-030310US	8388

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1627	

DATE MAILED: 09/27/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,869	PUNNONEN ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☑ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-40, drawn to a method for obtaining a polynucleotide that has a modulatory effect on an immune response, classified in class 435, subclass 6.

II. Claims 41-46, drawn to a method of obtaining a polynucleotide that encodes an accessory molecule, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different and distinct methods. Group I relates to a method of obtaining an optimized polynucleotide. Group II relates to a method of obtaining an accessory molecule.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Should applicants elect Group I, applicants are required to elect from the following methods:

1. Method of creating a library (e.g., claims 1 and 4)

2. Method of screening

3. Composition comprising of the optimized polynucleotide and genetic vaccine vector or method of administering said composition (e.g., claims 3 and 15).

Each of these methods is distinct in that the method of creating a library requires different process steps and uses different components from that of the screening. Screening requires a receptor or a target to react with the created library. Thus, the method of creating does not require the additional component of screening i.e., a target or a receptor. The method of administering or making a composition of the obtained optimized library of polynucleotide i.e., after screening requires additional component of the composition

besides the genetic vaccine vector e.g., a carrier to transport the genetic vaccine. Thus, while claim 1 recites for a single method step however, the steps incorporate three different, distinct and independent processes. Each of these processes (Subgroups 1-3) requires different starting materials, different steps, and different components and produces a different result. Applicants' incorporation of all the three distinct and different methods into a single claim makes this restriction proper. [Note that the claims provide for confusion as there are too many different methods being claimed. For example, it is not clear whether the method of creating the library as in claim 1, is the same or different from the method of creating the obtained optimized library of claim 5.]

Should applicants elect Subgroup 1, **method of producing**, applicants should further elect from the following species:

A. Recombinant polynucleotides created by the process recited in claim 4:

a. DNA shuffling

b. Error-prone PCR

c. Oligonucleotide-directed mutagenesis

d. Uracil-mediated mutagenesis

e. Repair-deficient host mutagenesis

d. Method of producing an optimized polynucleotide by recombining a plurality of n. a. as recited in claim 5.

f. Method of producing an optimized polynucloeitde by recombining with a further nucleic acid as recited in claim 6.

Each of these methods of producing is distinct in that the method steps for each of a-f requires different steps. For example, step b requires polymerase chain polynucleotide reaction while step c requires mutation of each of the nucleotide present in e.g., library that can be random or biased.

Should applicants elect subgroup 2, **screening method**, applicants are required to elect from the following species:

A. Recombinant interaction with a cellular receptor (claim 7) or non-cellular receptor.

a. If with a cellular receptor, elect species of cellular receptor:

i. Macrophage scavenger receptor (claim 8)

ii. Cytokine receptor (claim 9)

iii. Chemokine receptor (claim 9)

B. Screening wherein the encoded polypeptides:

i. Produced as fusion displayed on the surface of a bacteriophage (claim 12)

Applicants should further elect for the replicable genetic package:

a. bacteriophage (either gene III or gene VII)

b. cell

c. spore

d. virus

ii. Agonist (claim 7)

iii. Antagonist of a receptor (claim 7)

iv. The polypeptide mimics the activity of a natural ligand (claim 11)

C. Screening as recited in each of claims 29-33.

Should applicants elect subgroup 3, **a composition of the optimized product or a method of administering:**

A. Optimized products (of the composition) are:

i. peptides or polypeptides

ii. polynucleotides that encodes:

a. polynucleotide inserted into an antigen-encoding sequence of a genetic vaccine vector (claim 17)

b. Polynucleotide that encodes an M-loop of an HbsAg polypeptide (claim 18)

c. Rich in unmethylated CpG(claim 19)

d. Encodes a peptide that inhibits an allergic reaction.

If d is elected, elect the polypeptide:

i. Interferon

ii. IL

iii. antagonist of IL-4 or IL-5 or IL-13 or IL-10

If IL-10 is elected:

1. Soluble

2. Defective IL-10 or IL-20/MDA-7

e. Encodes a costimulator (claim 24)

1. costimulator is B7-1

2. B7-2 (claim 25)

3. CD1, CD40, CD154, CD150 (claim 26)

4. cytokine (claim 27)

If cytokine, elect from claim 28 e.g., IL-1-18, GM-CSF etc.

f. encodes a cytokine antagonist (claim 36)

a. Soluble cytokine receptor

b. Transmembrane having a defective signal sequence

c. IL-10r or -4R(claim 38)

g. Encodes a polypeptide capable of inducing a predominantly Th1 immune response (claim 39) or Th2 response (claim 40)

Should applicants elect **Group II,** applicants are required to elect:

A). Method of creating a library of recombinant

B). Method of screening

Elect the species of accessory molecule:

A. Proteasome or TAP (claim 43)

B. Cytotoxic cell (claim 44)

C. Immunogenic agonist sequence (claim 46)

Each of the methods in each of the subgroups is distinct because each of the species differs in structure and effects.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species from each of the subgroups 1-3 and the groups encompassed by the subgroups for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 41 are generic.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to M. Powers on 9/19/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1627

tdw
September 25, 2002